K043122

FEB - 9 2005

510(k) Summary

Date of Application:	November 1, 2004
Manufacturer:	Siemens AG A&D SE DT – Display Technologies 84 Siemensallee Karlsruhe, Germany 76187
Contact Information:	George Scott Marketing Manager, U.S. Siemens Display Technologies Ph: 303-604-6760 Fax: 303-664-0727 Email: george.scott@siemens.com
Classification Name:	System, Image Processing
Common/Usual Name:	Image Display Device, Medical Imaging
Proprietary Name/Model:	SMD 21500 or DSB-2103-D-5MP – 5M Pixel Grayscale Flat Panel Display
Device Ordering Codes:	6GF6201-4Cxxx (where xxx represents specific customer version)
Classification Number:	21 CFR 892.2050/Procode 90LLZ
Substantial Equivalence:	Barco Coronis 5MP HD (K041508)
Device Description:	The SMD 21500 / DSB-2103-D-5MP is a grayscale diagnostic medical display
Intended Use:	The SMD 21500 / DSB-2103-D-5MP device is intended to be used in displaying and viewing digital images for review by trained medical practitioners. It is especially designed for digital mammography applications.
Technological Characteristics:	The SMD 21500 / DSB-2103-D-5MP device is a high-resolution display with electronic capabilities for evaluation of high-resolution medical images. (See separate comparison chart to predicate device)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Siemens AG
% Mr. George Scott
Marketing Manager
Siemens Energy & Automation, Inc.
Power Control Division
515 Courtney Way, Suite A
LAFAYETTE CO 80026

Re: K043122
Trade/Device Name: SMD 21500 / DSB-2103-D-5MP
5M Pixel Grayscale Flat Panel Display
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: January 18, 2005
Received: January 18, 2005

Dear Mr. Scott:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number: K043122

Device Name: SMD 21500 / DSB-2103-D-5MP – 5M Pixel Grayscale Flat Panel Display

Indications for Use: The SMD 21500 / DSB-2103-D-5MP device is intended to be used in displaying and viewing digital images for review by trained medical practitioners. It is especially designed for digital mammography applications.

Prescription Use ✓

David A. Lyman
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K043122